DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 29, 2015

Covidien llc
Jenny Jiang
Regulatory Affairs Manager
161 Cheshire Lane, Suite 100
Plymouth, MN 55441

Re: K142839
Trade/Device Name: GenCut™ Core Biopsy System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOQ
Dated: April 2, 2015
Received: April 3, 2015

Dear Ms. Jiang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142839

Device Name
GenCut™ Core Biopsy System

Indications for Use *(Describe)*
The GenCut core biopsy system is utilized through a flexible endoscope or with the superDimension™ navigation system by physicians who are trained in endoscopic techniques for retrieving specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Covidien llc
Traditional 510(k)
GenCut™ Core Biopsy System

1. Submitter

510(k) Submitter:
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Date Prepared: 4/28/2015

2. Device

Trade Name :	GenCut™ Core Biopsy System
Common Name:	Core Biopsy System
Model Number:	SDCT01
Classification Name:	Bronchoscope (flexible or rigid) and accessories 21 CFR Part 874.4680
Product code:	EOQ

3. Predicate Device

Primary Predicate Device

Device Name :	Wang Transbronchial Aspriation Needle
510(k):	K914181
Classification Name:	Bronchoscope (flexible or rigid) and accessories 21 CFR Part 874.4680
Product code:	EOQ
Manufacturer:	ConMed Corporation

Secondary Predicate Device

Device Name :	eXcelon™ Transbronchial Aspiration Needle
510(k):	K040018
Classification Name:	Bronchoscope (flexible or rigid) and accessories 21 CFR Part 874.4680
Product code:	EOQ

Manufacturer: Boston Scientific

4. Device Description

The GenCut™ core biopsy system (GenCut system) is an endobronchial biopsy system that consists of a core biopsy tool, extension tube, locking syringe, and a tissue removal brush. The GenCut system is intended to retrieve tissue specimens from lungs during an endobronchial lung biopsy procedure. The product is used either through a flexible endoscope or in conjunction with the superDimension™ navigation system (cleared under 510(k) K092365).

The core biopsy tool is comprised of a polymeric shaft with steel braid reinforcement and a stainless steel side-cutting tip. The extension tube connects to the proximal end of the core biopsy tool shaft via a connection hub. The extension tube fittings allow the user to provide suction to the shaft via the supplied syringe. Upon completion of sampling, the tissue removal brush can be inserted through the length of the shaft to collect any remaining tissue not expelled through aspiration.

The product is packaged in a Tyvek pouch and sterilized with ethylene oxide. The product package contains the core biopsy tool and the following associated accessories:

- Extension tube
- Locking syringe
- Tissue removal brush

5. Indications for Use

The GenCut core biopsy system is utilized through a flexible endoscope or with the superDimension™ navigation system by physicians who are trained in endoscopic techniques for retrieving specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

6. Summary of Characteristics Compared to Predicate Devices

Both the subject device and predicate devices have the same technological principle.
All of these tools are advanced into the body through a flexible endoscope or other working channel. Once they reach the target biopsy site, suction is applied through a syringe and a sample is taken from the desired site. Once the sample is obtained, the devices are withdrawn from the body and a sample can be expelled from the tool.

Overall, the subject and predicate devices are all based on the following same technological elements:

- Device introduced endoscopically and used to reach the target site

- Device inserted through a flexible endoscope or other working channel
- Use of a distal tip to collect tissues and a syringe to aspirate samples out of the shaft
- Device intended for short-term introduction and transient use through a naturally occurring orifice

See table below for a detailed summary of the characteristics compared to the predicate device.

Characteristic	**GenCut system (Subject Device) K142839**	**Wang Transbronchial Aspiration Needle (Predicate Device)** K914181
Device Classification	Class II	Same
FDA Product Code	EOQ	Same
Technological Characteristics		
Anatomical Site	Lung	Same
Introduction to Target Tissue	Endobronchial Delivered to target tissue through a working channel	Same
Specimen Sampling Mechanism	Repeated axial motion with applied suction through a working channel	Same
Cell Collection	Aspiration with a syringe	Same
Working Outer Diameter	1.8 mm	1.9 mm
Working Length	106 cm - 115 cm	130 cm
Shaft Marks	Present	No
Tip	Blunted	Sharpened
Retractable Distal End	No	Yes
Radiopaque Distal End	Yes	Same
Material		
Working Outer Material	Polymer – Copolyester Elastomer Braid – 304 Stainless Steel	PTFE
Tip Material	Stainless Steel	Same

The following technological differences exist between the subject and predicate devices:

- The GenCut core biopsy tool contains a blunt distal tip with a side-cutting mechanism to facilitate tissue sampling while the primary predicate device features sharp distal tip with an end-cutting mechanism.
- The GenCut core biopsy tool has a polymeric shaft with steel braid reinforcement. The primary predicate device features a PTFE sheath.

In conclusion, the GenCut™ Core Biopsy System is technologically equivalent to the predicate device.

7. Performance Data

Non-clinical performance testing has been performed on GenCut system and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- ISO 10993-1:2009(Corr: 2010) Biological evaluation of medical devices – Part 1: Evaluation and testing
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7:2008(Corr:2009) Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity
- FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993 "Biological Evaluation fo Medical Devices Part 1: Evaluation and Testing" May 1, 1995

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility Data:

Biocompatibility testing was successfully completed in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993 "Biological Evaluation fo Medical Devices Part 1: Evaluation and Testing" May 1, 1995 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" as recognized by FDA. The following tests were conducted:

- Cytotoxicity
- Sensitization
- Intracutaneous Study

Design Verification and Validation Testing Data:

- Tensile Testing
- Shelf Life Testing
- Simulated Use Testing

- Packaging and Distribution Testing
- Dimensional Testing

Animal Study Data:
A preclinical study was conducted in a porcine model undergoing an endobronchial lung biopsy procedure. Three physicians including two pulmonologists and one thoracic surgeon conducted the study. All acceptance criteria were met. Therefore, the design of the GenCut system meets the intended use.

8. Substantial Equivalence Discussion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate devices, the proposed GenCut system has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.